

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0280]

DMB

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Certifier M. Hawkins

**Agency Information Collection Activities; Submission for OMB Review;  
Comment Request; Filing Objections and Requests for a Hearing on a  
Regulation or Order**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

## Filing Objections and Requests for a Hearing on a Regulation or Order (OMB Control Number 0910-0184)—Extension

The provision in 21 CFR 12.22, issued under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)(2)), sets forth the instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d) (21 CFR 12.20(d)). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection, for which a hearing has been requested, must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and do not limit the evidence that may be presented if a hearing is granted. Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

In the **Federal Register** of July 8, 2002 (67 FR 45125), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

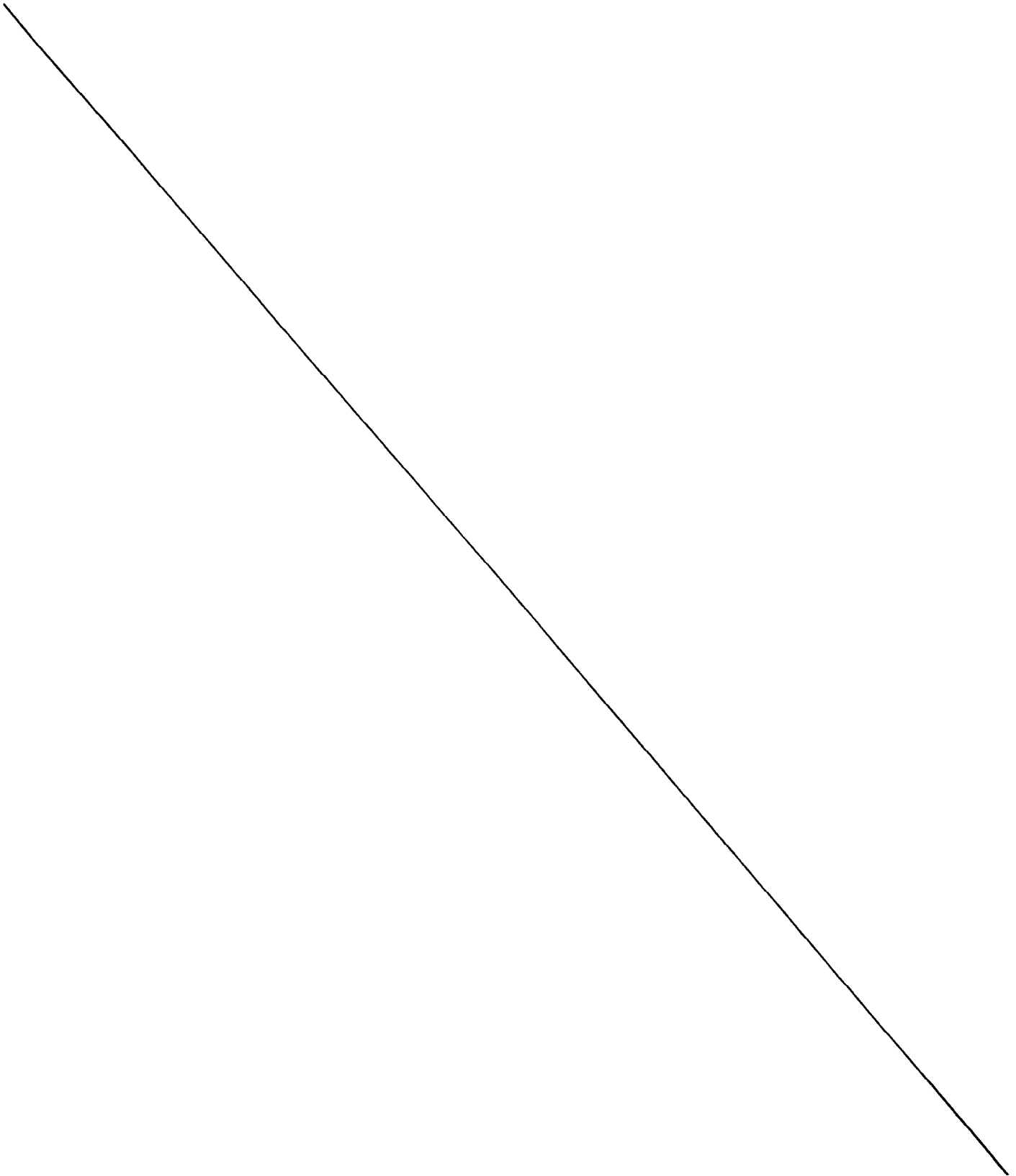
FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.22	10	1	10	20	200

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

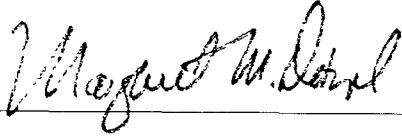
The burden estimate for this collection of information is based on past filings. Agency personnel responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order, estimate



approximately 10 requests are received by the agency annually, with each requiring approximately 20 hours of preparation time.

Dated: 11-21-02

November 21, 2002.



Margaret M. Dotzel,  
Assistant Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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